The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

NOV 15 2006

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SVETLANA SHCHEGROVA, WILLIAM O. FISHER, and PETER G. WEBB

Appeal No. 2006-2664
Application No. 10/061,800

ON BRIEF

Before ADAMS, MILLS, and LINCK Administrative Patent Judges.

Per Curium

ERRATUM

In the decision mailed October 21, 2006, we inadvertently omitted 2 references from the Appendix. These references are attached.

BOARD OF PATENT APPEALS
AND INTERFERENCES

Frances Hun for Dale Shaw
DALE M. SHAW
Acting Chief Appeals Administrator
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News Releases
- Industrial Commentary
- News from English Publications about ITRI
- News Archives
- Spotlight Archives

Implementation of Phalanx Microarray Technology-

- Fruition of ITRI's Multidisciplinary Effort in Biotechnology

Background

The research field of molecular biology began with the discovery of DNA structure in 1953, and has gained a great wealth of knowledge and revolutionized the study of biology and medicine. The more application-oriented side is biotechnology, which in recent years has caught the world's attention as a steady stream of success stories on cloning, genetic modification and human genome project appears in the news. Researchers in biotechnology are continuously searching for devices and methods with better precision and higher throughput.

DNA Microarrays

With the availability of whole genome sequences, many tools were developed to study biology on a whole-genome scale. The DNA Microarray, or Gene Chip, is the most important invention of them all. A DNA microarray is a slide (a few square centimeters) that contains many different kinds of DNA (called "probes") deposited on its surface, each based on a certain gene from a genome of interest. The probes on the slide usually are arranged in an array, each address (or spot) on the DNA microarray corresponds to a specific gene. The probe on the slide can grab or "hybridize with" the complementary DNA or RNA fragments (called "targets") generated from the testing sample. By measuring the fluorescent intensity on a probe location after hybridization, one can estimate the expression activity of a specific gene in the testing sample.

Manufacturing Processes for DNA Microarrays

Currently there are two basic ways of making DNA microarrays: the in-situ

synthesis and the spotting methods.
The in-situ method performs the direct synthesis of DNA molecules on the surface of the microarray slide. Tens of thousands of DNA synthesis reactions are carried out simultaneously on the slide surface. There are two different in-situ synthesis methods, i.e., photolithography and inkjet printing. The photolithography method borrows technology developed in the semi-conductor industry. A series of specially designed photo-masks are used to introduce in sequence the photoactive analogs of the four DNA nucleotides (A, C, T, and G) into the synthesis reactions. The other in-situ method uses the inkjet printing mechanism to deliver the DNA nucleotides onto the probe location. The inkjet-head movement is computer-controlled to ensure the accuracy of the nucleotide deposition process. For both methods, the quality of the DNA is very difficult to monitor or control. They also suffer from high manufacturing cost and low production capacity. The unit price ranges from US$500 to US$2,000.
In the spotting method, the probes are synthesized before they are applied to the microarray surface. The probe is usually synthesized by polymerase chain reaction (for the longer cDNA probe) or by a conventional DNA synthesis method. The probes are then spotted on the slide and immobilized through various surface chemistry mechanisms. The effectiveness of this method is highly dependent on the design of the arraying equipment and the surface chemistry between the probe solution, the dispensing apparatus, and the slide surface.
Currently there are many robotic microarrayers and microarray slides available on the market for smaller scale production. The systems are usually set up by the microarray core facility of research institutes for in-house usage. The throughput and the production size are relatively low, so the unit cost stays high. The quality of the microarrays is inconsistent, making comparison between various microarray experiments very difficult if not impossible. ITRI has now come up with a manufacturing scheme that combines the advantages of in-situ and spotting methods, resulting in significantly higher throughput and lower cost.

ITRI's Phalanx Microarray Technology - a High Throughput Manufacturing Process

In 1998, theBiomedical Engineering Center (BMEC)of ITRI initiated the Biochip Project to explore the potential of microarray technology. The multidisciplinary research team of the project came from 5 different research ITRI divisions, including BMEC,Opto-Electronics & Systems Laboratories (OES),Center for Measurement Standards (CMS),Union Chemical Laboratories(UCL), andElectronics Research & Service Organization (ERSO). The project has led to a multitude of patents, covering the subjects of surface chemistry, microdispenser, microarray, and electrophoresis. The collective result of the project is the phalanx microarray technology, which is a high throughput manufacturing process that can produce reliable, high-quality microarrays with a density of 4,000 pre-synthesized probes per cm2 at low cost, perhaps as low as one-tenth of that of the current product

The core of the phalanx microarray technology is the Phalanx Jet liquid micro-dispenser, Phalanx Arrayer, and Phalanx Slide. The Phalanx Jet and Phalanx Array were co-developed by BMEC and OES. The Phalanx Jet

employs bubble jet printer technology to precisely dispense micro-volume liquid at very high density. The Phalanx Arrayer is an automatic arraying platform that can be assembled into a continuous arraying pipeline with high precision and throughput. BMEC and UCL co-developed the surface chemistry for the Phalanx Slide that enables the DNA solution to maintain a uniform contact surface and to maximize the DNA immobilization on the slide surface.

The Founding of Phalanx Biotechnology Group, Inc.

Due to the great success of the Biochip Project, ITRI and other local biotech businesses formed the Biochip R&D Alliance to pursue the accompanying commercial opportunities. To make the best use of the Project's IP, ITRI put together an IP bundle and licensed it exclusively to the new start-up formed by that Alliance. The Alliance has invested an aggregate of 500 million NT dollars to create Phalanx Biotech Group, Inc. (PBG) to implement the micro-array production technology, staffed mainly by members from the Project.

PBG will have a pilot product Phalanx Human Liver 2000 Microarray, which contains about 2000 probes for liver related genes, by April 2003. It will begin producing Phalanx Human Whole-Genome Microarray (PHWGM), containing more than 30,000 probes that cover all known genes in human genome, by the end of 2003. PBG will design all the probe sequences collaboratively with ITRI using BMEC's bioinformatics software, which will incorporate the most updated human genome information. PBG will also continue to work with BMEC to adopt state-of-the-art quality control concepts into microarray production, such as using MALDI-TOF mass spectrometry to validate the integrity and identity of every probe on the microarray. Furthermore, PBG will continue to work in partnership with other ITRI divisions for the improvement in phalanx microarray technology.

Related Link: http://www.bmec.itri.org.tw/english/main.htm

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Last Updated: 08/31/2006

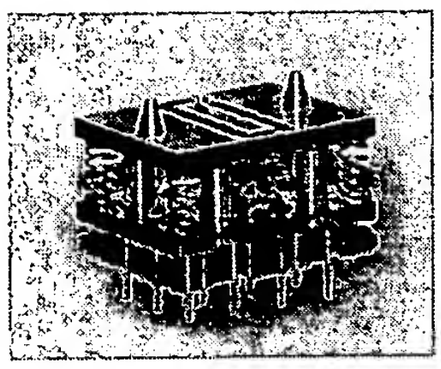
Aj Arrayjet

High Quality Microarray Production Powered by Ink

History

Arrayjet ® Ltd was founded in August 2000 by a Cambridge physicist, Dr. Howard Mann of Edinburgh molecular biologists, Prof. Peter Ghazal and Dr. Douglas Roy, to develop ro printheads to make biological microarrays. In February 2001 Arrayjet secured two-stag Scotland based investor group known as Archangels and won a Scottish Enterprise develop the ink jet microarray platform. Further funding by Archangels and SE followed.

Dr. Manning is Arrayjet's Technical Director and Keith Howell, an Edinburgh based direct is Chairman. Professor Ghazal is chief scientific advisor and Dr Roy is lead advisor on engineers have been recruited, premises located close to Edinburgh and a labora professional alliances have been formed.



Arrayjet was at first engaged in product development. In the period from February 200: year the fundamental technology behind Arrayjet was demonstrated, and milestones set the first round of funding were met. Subsequent funding supported the design, commissioning of a pre-production prototype.

Arrayjet has now launched a number of products into the microarray market and contin technology.

ARRAYJET is not licensed under any patents owned by Oxford Gene Techn related companies ("OGT") and cannot pass any such licence to its customers OGT's patents may be necessary to manufacture or use oligonucleotide arrays.

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